JUN 11 1999

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RICHARD WOLF
MEDICAL INSTRUMENTS CORPORATION

510(k) Summary of Safety and Effectiveness

Submitter:			**Date of Preparation:** April 5, 1999
Company / Institution name: **Richard Wolf Medical Instruments Corp.**			FDA establishment regulation number: 14 184 79
Division name (if applicable): N.A.			Phone number (include area code): (847) 913-1113
Street address: 353 Corporate Woods Parkway			FAX number (include area code): (847) 913-0924
City: Vernon Hills	State/Province: Illinois	Country: USA	ZIP/Postal Code: 60061
Contact name: Mr. Robert L. Casarsa			
Contact title: Quality Assurance Manager			

Product Information:	
Trade name: Flexible Fiberscope	Model number: 7331.001
Common name: Flexible Fiberscopes	Classification Name: Flexible Endoscopes

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K980401	1 Flexible Fiberscopes	1 Richard Wolf
2 K963855	2 Compact Operating Ureteroscopes & Uretero-Renoscopes Devices (URS)	2 Richard Wolf
3	3	3
4	4	4
5	5	5
6	6	6

1.0 Description

The flexible fiberscopes consist of a flexible insertion part, a control part, a bent eyepiece for direct view or connection of a video camera and straight working channel, especially for the use with lithotripsy probes.

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2.0 Intended Use

The flexible fiberscopes are used to examine body cavities and hollow organs via natural accesses or surgically created accesses.

3.0 Technological Characteristics

There are no significant technological characteristic changes to the new devices when compared to the existing devices.

The tip of the sheath has an active 130° / 160° up/down. The image is transmitted via objective, fiber bendle and eyepiece for direct view or connection of a video camera. The straight working channel is used for procedures such as lithotripsy and biopsy removal while simultaneously providing irrigation. The bent eyepiece funnel can be moved to the right or left. Auxiliary instruments, such as gaping forceps, sone extractors, or HF button electrodes are inserted by a proximal mounted insertion cock with supply and discharge. A leakage test unit or a gas sterilization valve can be connected to an attachment of the fiberscope.

4.0 Substantial Equivalence

The submitted devices pose the same type of questions about safety and effectiveness as the compared devices. The new technological characteristics have not diminished safety or effectiveness. The submitted devices are substantially equivalent to existing pre-enactment and 510(k) devices sold by Richard Wolf (K980401, K963855).

5.0 Performance Data

No known FDA performance standard exists.

6.0 Clinical Tests

No clinical tests performed.

7.0 Conclusions Drawn

These devices are designed and tested to guarantee the safety and effectiveness when used according to the instruction manual.

By: Robert L. Casarsa Date: Mar 31, 99

Robert L. Casarsa
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 1999

Mr. Robert L. Casarsa
Quality Assurance Manager
Richard Wolff Medical
Instruments Corporation
353 Corporate Woods Parkway
Vernon Hills, IL 60061

Re: K991178
Flexible Fiberscope
Dated: April 5, 1999
Received: April 7, 1999
Regulatory Class: II
21 CFR §876.1500
Product Codes: 78 FGB/78 KOG

Dear Mr. Casarsa:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K991178

Device Name: Flexible Fiberscope

Intended Use:

The flexible fiberscopes are used to examine body cavities and hollow organs via natural accesses or surgically created accesses.

Indications and Field of Application:

For examination, diagnosis, and / or therapy in connection with endoscopic accessories and auxiliary instruments, in particular, for intracorporal flexible lithotripsy probes, e.g., pneumatic or electrohydraulic, used through the working channel of the instrument.

The instruments are used in the medical disciplines of urology, surgery, gynecology, and ENT by adequately trained and qualified medical personnel. Applications to the heart, the central nervous system, and the circulatory systems are excluded.

Important! Product dimensions must correspond to the anatomic requirements, i.e., use the flexible fiberscope appropriate to the medical discipline.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K991178

Prescription Use ✓ OR Over-The Counter

Per 21 CRF 801.109

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Contraindications:

Contraindications directly related to the product are currently unknown. Based on the patient's general condition, the attending physician must determine if the application is appropriate. For further information refer to the latest medical literature.

Combinations:

The flexible fiberscopes are used in combination with light sources and flexible light cables, video cameras, or reflex cameras and lenses/objectives, suction irrigation devices, as well as endoscopic accessories (flexible lithotripsy probes, forceps, HF instruments, sheaths laser fibers, etc.).

Caution! Ensure devices used in combination are compatible n their intended use and relevant specifications, e.g., working length, diameter, etc. Comply with the device instruction manuals used in combination with the submitted devices.

Important! If the fiberscopes are used as uretero-renoscopes or in choledochus revisions, they must be placed via a guide wire.

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